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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,366	08/29/2006	Robert D. Black	9099.17	3158

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MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
NGUYEN, HIEN NGOC	
ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,366	BLACK ET AL.	
	Examiner	Art Unit	
	HIEN NGUYEN	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15-23,34 and 41-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15-23,34 and 41-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09/29/2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3, 5-7, 10, 13, 15-18, 20-23, 34, 41-45, 48, 50-51, 53 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) and in view of Allen et al. (US 4,945,914).

3. Addressing claim 1, Mate discloses: a target locating and in vivo sensor system used with a therapy delivery and imaging source (see [0001] and [0009-0014]); an external solenoid member (see [0032-0039] and [0041-0048]); at least one implantable wireless unit such as a solenoid, the solenoid held internally in the patient cooperates with the external solenoid to generate a coupling signal having signal strength that varies based on the position of the external solenoid member relative to the implanted unit (see [0041-0048] [0050], [0056-0061]); a computer module in communication with the controller comprising computer program code that evaluated the coupling signal strength in relation to the position of the external solenoid and determines the position of at least one internally implanted unit (see [0009-0014] and [0053]). However, Mate does not disclose a mechanism configured to controllably move the solenoid external of

a patient, a controller configured to direct the movement of the mechanism and the controller is in communication with a power source. In the same field of endeavor, Allen discloses a mechanical arm configured to hold and move a sensor which is a solenoid external of a patient (col. 15, lines 12-27, robot arm element 34 and sensor/solenoid element 40). It is inherent the robot arm has a controller configured to direct the movement of the mechanism/robot arm and the robot arm is in communication with a power source because without controller and power source the robot arm can not move. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Mate's system to include a mechanism (robot mechanical arm) that is connect to a power source and has a controller to control its movement and the movement of the solenoid external to the patient as taught by Allen because with the robot mechanical arm and sensor/solenoid at its tip surgeon can effectively keep track of the solenoid/fiducial implant inside the body.

4. Addressing claims 2-3, 5-7, 10, 13, 17-18, 20-22, 50-51 and 53, Mate discloses the coupling signal is a magnetic coupling signal (see [0036]); the system is capable of using the frequency of 500khz-1Mhz (this is just AC frequency supply to the external solenoid; the system can supply frequency in this range to the external solenoid). It would have been obvious design choice to one of ordinary skill in the art at the time of the invention to design the system to detect coupling signal at a depth of up to at least about 14 cm because this enable implant to be deeply implanted anywhere inside the patient body and only require routine skill in the art. Mate use excitation markers and

sensors to identify and track the position of the target and guide radiation beam. Internal excitation marker is located in or near the target. An external excitation source that is remotely excites the markers to produce an identifiable signal. Allen discloses the mechanisms is an articulated arm and wherein the articulating arm is configured to move the sensor in a three-dimensional pattern in free space to generate the coupling signal (see col. 4, lines 9-68).

5. Addressing claims 15-16 and 48, it would have been obvious to one of ordinary skill in the art at the time of the invention that Mate's system in view of Allen perform the functions in claims 15-16 and 48 because the system has to evaluate signal shape and strength coming from internal sensor in order to locate the internal sensor position. As disclose by Allen above in col. 15, lines 12-27, the robot arm is moving through three dimensional spaces to determine the position of the sensor inside the patient body. The robot arm is moving to find the implant and come into contact with the implant.

6. Addressing claims 23 and 41, the method claim herein is substantially the same in scope as the system in claims 1 and 7 above. The system applied the method. Thus claim 23 and 41 are rejected for at least the same reason as claims 1 and 7 above. Also see Mate [0009]. He tracks the position of the cancerous target and selectively applies radiation to the target. This is the same method as claim 41.

7. Addressing claim 42, Mate discloses positioning the patient in an imaging system in a registered position and obtaining an image of the target treatment site and at least one implanted sensor with the patient in the registered position in an imaging system (see [0060], the image show target site 12 and markers 30 therefore it is inherent the patient is in a registered position in order to have images of target site and markers). Allen discloses aligning the coupling member to a fiducial marker associated with the imaging system relative to the registered position and obtaining an electrical measurement of signal strength of the coupling signal while the patient is in the registered position and the coupling member is aligned to define the initial spatial position of the at least sensor unit in three-dimensional space (see col. 15, lines 12-52). The sensor on the tip of the robot arm finds the fiducial implant and touches it. The coupling member is the sensor on the tip and it aligns with the fiducial marker by touching it. Sensor on the tip has to use electrical measurement of signal strength of the coupling signal in order to find the fiducial marker. The sensor unit is the fiducial marker and the sensor on the tip is aligning with the sensor unit in three dimensional spaces.

8. Addressing claims 34, 43-45 and 54-57 and the computer program claim herein is substantially the same in scope as the system in claim 1, 21-22 and 49 above. The system of claims 1, 21-22 and 49 runs the computer program in claims 34, 43-45 and 54-57. Thus claims 34, 43-45 and 54-57 are rejected for at least the same reason as claims 1, 21-22 and 49 above. Also see Mate [0009] and [0036], he discloses guiding

radiation therapy, selectively transmit radiation dose using implanted sensor. He has to have computer program in order for the system to perform this function.

9. Claims 4, 8-9, 11-12, 19, 46-47 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685), in view of Allen et al. (US 4,945,914) and further in view of Knapp et al. (WO 97/33513).

10. Addressing claims 4, 8-9, 11-12, 19, 46-47 and 52, Mate and Allen do not explicitly disclose communicating with implanted sensor unit using a bit encoded RF signal, sensors with sensing parameter for temperature and radiation dose. Knapp discloses: the external reader is configured to communicate with the implanted sensor unit using a bit encoded RF signal to communicate with many sensors, by using bit encoded Knapp can identify and separately communicate with each sensor (see abstract, page 3, lines 1-33, especially lines 4, 10 and 12, the hand held electromagnetic reader is the external reader; the transmitted encoded data is the bit encoded RF signal; this is wireless encoded data therefore it has to be bit encoded RF signal) at least one sensing parameter is a radiation dose for sensing radiation inside a body (see page 9, lines 30-36); at least one sensing parameter is a temperature for sensing temperature inside the body (see page 9, lines 30-36); the plurality of sensor units are configured to relay data regarding radiation dose and temperature to the reader (see page 9, lines 1-29). Mate in view of Allen and Knapp provide a therapy system to provide real time dynamic spatial position data and selected internal parameter data of a target region thereto base on data from the at least one sensor and

the coupling signal. There has to be a computer program in order for the system to perform this function. Mate and Allen from claims above provide tracking position data from sensor signal which is the same as dynamic spatial position data from sensors and coupling signal and Knapp provided selected internal parameter data such as radiation and temperature from implanted sensor. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Mate's system to include bit encoded RF signal and sensors as taught by Knapp in order to allow the system to identify and separately communicate with sensors for sensing temperature and radiation dose inside the patient body.

Response to Arguments

Applicant's arguments filed 04/09/2010 have been fully considered but they are not persuasive. Applicant argues Allen does not disclose electrically couple a solenoid on the robotic arm with the fiducial implant to provide a coupling signal that is used to determine the position of the implant. Applicant's argument is not persuasive because examiner only relies on Allen to disclose a robot mechanical arm and sensor/solenoid at its tip so surgeon can effectively keep track of the solenoid/fiducial implant inside the body (see col. 15, 11-20, the sensor element 40 keep track of the implant element 10) and Mate discloses coupling signal between external and internal solenoid to keep track of the internal solenoid.

Applicant argues it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Mates in view of Allen because this would appear

to be modified to use a moving arm with a tip sensor and with fixed location fiducial makers. Applicant's argument is not persuasive because the internal fiducial markers (solenoid) discloses by Mates is not fixed. The markers are fixed to the target tissue, however, the tissue move therefore the markers also move (see [0005-0009] and [0033]). Further, Mates and Allen are in the same field of endeavor which is locating the fiducial implant therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the references to improve tracking/locating the fiducial implant.

Applicant argues the references do not disclose limitation detecting coupling signal at a depth of up to at least about 14 cm in claims 6 and 13. This limitation is being addressed in the rejection section above. Please see the rejection section for explanation.

New claims 49, 50-51 and 57 are being addressed in the rejection sections above.

Addressing claims 3, 15-16 and 34, applicant argues the references do not disclose moving articulate arm with external sensor/solenoid in 3D space to generate coupling signal shape. Applicant's argument is not persuasive because Allen discloses a moving articulate arm in 3D space with external sensor (col. 15, lines 11-20) and Mates discloses generating coupling signal shape from external and internal solenoid (see [0035] and [0037-0039], moveable gantry element 20). When current is passing through solenoid magnetic field is created. When the solenoid move or rotate signal strength and shape changes. One of ordinary skill in the art at the time of the invention

would recognize that in order for the external magnetic sensor/solenoid and internal marker/solenoid to communicate and determine position and orientation the system must detect magnetic coupling signal strength or shape.

Mates essentially discloses guiding radiation therapy beam using internal and external magnetic sources. However, Mates does not explicitly disclose articulate moving arm with tip sensor and bit encoded RF signal. Allen and Knapp disclose these missing limitations. Mates in view of Allen and Knapp disclose the applicant's invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HIEN NGUYEN whose telephone number is (571)270-7031. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768